

Message

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**From:** Webster - CDPHE, Tara [tara.webster@state.co.us]  
**Sent:** 4/8/2022 10:05:45 PM  
**To:** Hicks, Kerry [Hicks.Kerry@epa.gov]  
**CC:** kristy.richardson@state.co.us; paul.romerpresent@state.co.us; Rucker - CDPHE, Stefanie [stefanie.rucker@state.co.us]; Daniel Bon - CDPHE [daniel.bon@state.co.us]; garrison.kaufman@state.co.us; Olson, Kyle [Olson.Kyle@epa.gov]; Mylott, Richard [Mylott.Richard@epa.gov]; Khan, Barbara [Khan.Barbara@epa.gov]  
**Subject:** Re: FW: 114 Update- RE: EtO Terumo/CDPHE/EPA 114 Call

Hi Kerry,

For the tox team Monday except for 11-11:30am would be the best. Some of us will be traveling for a conference on Tuesday.

Best,  
Tara

On Fri, Apr 8, 2022 at 11:02 AM Hicks, Kerry <[Hicks.Kerry@epa.gov](mailto:Hicks.Kerry@epa.gov)> wrote:

We're planning to meet with Terumo BCT early next week. Which time do you all prefer?

**Monday, April 11, 2022**

9:30am-noon

**Tuesday, April 12, 2022**

11am – 5pm available

Kerry A. Hicks, PMP

Environmental Engineer

Air Toxics, Radiation & Modeling Branch

U.S. Environmental Protection Agency, Region 8

1595 Wynkoop St. Denver, CO 80202

Office: 303-312-6891

Mobile: 770-557-9605

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**From:** Done, Jessi <[Jessi.Done@terumobct.com](mailto:Jessi.Done@terumobct.com)>  
**Sent:** Friday, April 8, 2022 9:51 AM  
**To:** Hicks, Kerry <[Hicks.Kerry@epa.gov](mailto:Hicks.Kerry@epa.gov)>  
**Cc:** Olson, Kyle <[Olson.Kyle@epa.gov](mailto:Olson.Kyle@epa.gov)>  
**Subject:** RE: 114 Update- RE: EtO Terumo/CDPHE/EPA 114 Call

Hello,

Thank you for your email below. Would any of these times work for a scheduled meeting between us?

**Friday, 08 April 2022**

1:00pm-5pm available

**Monday, April 11, 2022**

9:30am-noon

**Tuesday, April 12, 2022**

11am – 5pm available

I look forward to a discussion with you. Thank you so much for this opportunity.

**Jessi Dōne, M.B.A., NRCM(RM)**

Sr Plant Mgr, Sterilization Services

Terumo BCT Sterilization Services, Inc.

Terumo Blood and Cell Technologies

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**From:** Hicks, Kerry <[Hicks.Kerry@epa.gov](mailto:Hicks.Kerry@epa.gov)>

**Sent:** Monday, April 4, 2022 7:58 AM

**To:** Done, Jessi <[Jessi.Done@terumobct.com](mailto:Jessi.Done@terumobct.com)>

**Cc:** Olson, Kyle <[Olson.Kyle@epa.gov](mailto:Olson.Kyle@epa.gov)>

**Subject:** [EXTERNAL] RE: 114 Update- RE: EtO Terumo/CDPHE/EPA 114 Call

Jessi,

We have finished modelling and are ready to share some of the results with you and your team. The information you all submitted with your 114 Information Collection Request was used and did decrease your modelled emissions. The risk has not disappeared due to the proximity of housing and the toxicity of EtO; however, it is significantly reduced. We would like to share these results with you and inform you of our steps forward in a meeting.

Please let me know your availability for later this week (Thursday and Friday) or next week. CDPHE will join us on the call as they are partnering with us they have from the beginning.

Thanks,

Kerry A. Hicks, PMP

Environmental Engineer

Air Toxics, Radiation & Modeling Branch

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**From:** Olson, Kyle

**Sent:** Thursday, February 24, 2022 1:35 PM

**To:** Done, Jessi <[Jessi.Done@terumobct.com](mailto:Jessi.Done@terumobct.com)>

**Subject:** RE: 114 Update- RE: EtO Terumo/CDPHE/EPA 114 Call

Fantastic, thank you for reaching out Jessi. Our HQ office is still modeling the data but we plan to work with the State of CO and you to check in on the outputs ASAP. We've been adamant that you all have installed additional controls and that that information is reflected in the data shared with the public. Let's definitely plan to meet in the coming week or so to go over where we are on this. I'll find out where they are with modeling and get back to you with a plan to meet.

Thank you again,

Kyle Olson

US EPA Region 8

1595 Wynkoop St.

Denver, CO 80220

303-312-6002

[olson.kyle@epa.gov](mailto:olson.kyle@epa.gov)

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**From:** Done, Jessi <[Jessi.Done@terumobct.com](mailto:Jessi.Done@terumobct.com)>

**Sent:** Wednesday, February 23, 2022 2:34 PM

**To:** Olson, Kyle <[Olson.Kyle@epa.gov](mailto:Olson.Kyle@epa.gov)>

**Subject:** FW: 114 Update- RE: EtO Terumo/CDPHE/EPA 114 Call

Hello, Kyle –

Terumo BCT Sterilization Services and the regional EPA office met back in November of 2021 to discuss emissions accuracy of the risk value of ethylene oxide from 2016/2017, which was being used to inform the Commercial EtO Sterilizer regulations. The regional EPA had an inclination that the modelers were possibly using data for Terumo BCT that may not reflect extent of the emission controls. There was a follow up meeting to be scheduled for early this year for follow up clarifications / questions from our November 2021 meeting. The goal was to have the opportunity to ensure the data accurate reflects our operation and with the EJScreening now reflecting the 2017 data on the website, this would be a good time to reconnect.

What is your availability for early March?

**Jessi Dōne, M.B.A., NRCM(RM)**

Sr Plant Mgr, Sterilization Services

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**From:** Olson, Kyle <[Olson.Kyle@epa.gov](mailto:Olson.Kyle@epa.gov)>

**Sent:** Friday, November 5, 2021 11:21 AM

**To:** Done, Jessi <[Jessi.Done@terumobct.com](mailto:Jessi.Done@terumobct.com)>

**Subject:** [EXTERNAL] RE: EtO Terumo/CDPHE/EPA 114 Call

Fantastic Jessi- I'll work with our HQ office on this and then get back to you. Thank you for sharing the presentation with those of us in the meeting (I'll keep it internal to that group), it will definitely help us to get you and your team the answers you need.

Thanks again,

Kyle Olson

US EPA Region 8

1595 Wynkoop St.

Denver, CO 80220

303-312-6002

[olson.kyle@epa.gov](mailto:olson.kyle@epa.gov)

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**From:** Done, Jessi <[Jessi.Done@terumobct.com](mailto:Jessi.Done@terumobct.com)>

**Sent:** Friday, November 5, 2021 11:05 AM

**To:** Olson, Kyle <[Olson.Kyle@epa.gov](mailto:Olson.Kyle@epa.gov)>

**Subject:** RE: EtO Terumo/CDPHE/EPA 114 Call

Hello, Kyle –

Thank you for meeting with the Terumo BCT and Terumo BCT Sterilization Services team yesterday. The presentation is attached, as promised.

It was great to meet you, the EPA and CDPHE teams. The partnership, the conversation, and the clarifications on the spreadsheet were very much appreciated. In particular, we appreciate that you understand the emissions modeling is artificially high and does not reflect our emission controls, and that you took initiative to reach out to our group for the correct data.

We look forward to hearing back from you on the follow up clarifications / questions. Also, please schedule the next meeting at your convenience. We are happy to have the opportunity to ensure the data accurate reflects our operation and that we can take credit for the outstanding engineering controls in place.

Please feel free to share the attached presentation with other meeting attendees.

Thanks again,

**Jessi Dōne, M.B.A., NRCM(RM)**

Sr Plant Mgr, Sterilization Services

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**From:** Olson, Kyle <[Olson.Kyle@epa.gov](mailto:Olson.Kyle@epa.gov)>  
**Sent:** Wednesday, November 3, 2021 10:53 AM  
**To:** Done, Jessi <[Jessi.Done@terumobct.com](mailto:Jessi.Done@terumobct.com)>  
**Subject:** [EXTERNAL] RE: EtO Terumo/CDPHE/EPA 114 Call

Hi Jessi-

Please forgive me for missing your email, and thank you for your willingness to meet up to help us get a handle on the emissions from Terumo BCT. Our HQ Office of Air Quality and Planning Standards has been working on revising the Commercial EtO Sterilizer regulations based on the updated risk value of ethylene oxide from 2016. Each regional office has been tasked with verifying that the emissions at each facility are in fact accurate, and it seemed to us that the modelers were possibly using data for Terumo BCT that may not reflect extent of your emission controls. Specifically, we were relieved that in 2018 Terumo BCT had gone above and beyond and had routed fugitive emissions through an existing dry scrubber, and it looked like the modeling inputs we're currently using may not reflect that change. Also, we'd talked with Jason Long at CDPHE and he'd mentioned that you all may be looking at installing a catalytic oxidizer sometime in 2022, and if possible we'd like to have those controls included in the risk modeling effort that supports the regulation revision. Looking forward to talking with you tomorrow, thank you in advance for your help verifying these emission numbers.

Kyle Olson

US EPA Region 8

1595 Wynkoop St.

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303-312-6002

[olson.kyle@epa.gov](mailto:olson.kyle@epa.gov)

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**From:** Done, Jessi <[Jessi.Done@terumobct.com](mailto:Jessi.Done@terumobct.com)>

**Sent:** Tuesday, November 2, 2021 5:17 PM

**To:** Olson, Kyle <[Olson.Kyle@epa.gov](mailto:Olson.Kyle@epa.gov)>

**Subject:** RE: EtO Terumo/CDPHE/EPA 114 Call

Good Evening, Kyle –

I did not see a response on the below, so I pulled together a small team to meet with you this Thursday, at 10am. We welcome the opportunity to connect with you and your team, but have questions on the inputs, and the basis of calculations and data on the spreadsheet attachment to the meeting invite. As part of the meeting we would like to gain an understanding on these points.



From our end these will be the attendees:

Manne, Varaprasad [Varaprasad.Manne@terumobct.com](mailto:Varaprasad.Manne@terumobct.com) Director of Manufacturing Operations

Romero, Christine [Christine.Romero@terumobct.com](mailto:Christine.Romero@terumobct.com) Communications Manager

Bartoletti, Vince [Vince.Bartoletti@terumobct.com](mailto:Vince.Bartoletti@terumobct.com) Sr. Manager, Global Sterilization

Jessi Done, Sr. Plant Manager, Terumo Sterilization Services

We look forward to meeting with you.

Regards,

**Jessi Dōne, M.B.A., NRCM(RM)**

Sr Plant Mgr, Sterilization Services

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-----Original Appointment-----

**From:** Done, Jessi

**Sent:** Thursday, October 28, 2021 6:38 PM

**To:** Olson, Kyle

**Subject:** New Time Proposed: EtO Terumo/CDPHE/EPA 114 Call

**When:** Thursday, November 4, 2021 10:00 AM-10:45 AM (UTC-07:00) Mountain Time (US & Canada).

**Where:** Microsoft Teams Meeting

Hi, Kyle –

Your meeting request has been received. I would like to propose meeting on Thursday, November 11<sup>th</sup>, as the Sterilization Services facility has a certification audit on November 3<sup>rd</sup> and 4<sup>th</sup>. Please let me know if you, and your team, would be available to accommodate an 11/11 meeting.

Much appreciated,

**Jessi Dōne, M.B.A., NRCM(RM)**

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**\*\* Statement from Terumo BCT, Inc. \*\***

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**\*\* End of statement \*\***

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Tara Webster, Ph.D.  
Environmental Health Educator  
Toxicology and Environmental Epidemiology Office



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